

REMARKS / ARGUMENTS

Claims 8 and 9 are pending. Claims 1–7 and 10-11 are cancelled without prejudice or disclaimer, and Applicant reserves the right to pursue the subjected matter in other applications.

Claims 8-9 are rejected for non-statutory obviousness-type double patenting based on claim 19 of U.S. Pat. No. 6,663,889 to Maerz. The Examiner asserts that a method for treating inflammation in the pharynx with ambroxol is not patentably distinct from a method of administering ambroxol with a suckable tablet because the method claimed in the current application is “obviously achieved upon the same method of administering the same active agent to the same subject by the patent.”

The Applicant respectfully disagrees with the Examiner and submits that the present invention as claimed is patentably distinct from claim 19 of the Maerz ‘889 patent. The Applicants acknowledge that the Examiner considered the Applicants’ previous remarks to be unpersuasive. The Applicants respectfully request reconsideration in light of the following additional remarks.

The present Application claims a method for treating inflammation in the pharynx comprising applying a pharmaceutical composition comprising ambroxol or one of the pharmacologically acceptable salts thereof to an inflamed pharynx to treat the inflammation of the pharynx.

In Perricone v. Medicis Pharm. Corp., 432 F.3d 1368, 1372 (Fed.Cir.2005), the Federal Circuit provided guidance concerning inherent anticipation of method claims. Citing Catalina Marketing International, Inc. v. Coolsavings.com, Inc. (289 F.3d 801, 809

(Fed.Cir.2002), the Court explained that a patent to an apparatus does not necessarily prevent a subsequent inventor from obtaining a patent on a new method of using the apparatus.

Following the Courts analysis, the Applicants respectfully submit that the claims of this Application recite a new method of using ambroxol, *i.e.*, treating of an inflamed pharynx. The claimed ambroxol lozenge of the Maerz '889 patent does not suggest application of ambroxol to an inflamed pharynx because applying ambroxol to an inflamed pharynx to treat inflammation is not analogous to applying ambroxol to the pharynx in general. There is an important distinction between application to the pharynx in general and the much more specific application to an inflamed pharynx. The Maerz '889 patent is silent about any inflammation treatment benefits, not to mention the mechanisms underlying such a use.

Because the Maerz '889 patent does not disclose or suggest application of ambroxol to an inflamed pharynx, the Applicant respectfully requests that the obviousness-type double patent reject of the claims based on the Maerz '889 patent should be reconsidered and withdrawn.

Claims 8-9 have been rejected under 102(b) as being anticipated by the Maerz WO publication and under 102(e) as being anticipated by the Maerz '889 patent. The Examiner asserts that treating inflammation of the pharynx would be an inherent effect of administering the same active composition to the same subject taught by the Maerz WO publication and the Maerz '889 patent. Under 35 U.S.C. section 102 (b) or 102 (e), anticipation requires that every element of the claim be disclosed within the cited reference. The Maerz WO publication and the Maerz '889 patent do not disclose treating inflammation in the pharynx, which is the purpose of the present method claims. Accordingly, the Applicant respectfully submits that the present invention as claimed is not anticipated by either the Maerz WO

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publication or the Maerz '889 patent. Therefore, the Applicant respectfully requests that the 102(b) and 102(e) rejections of claims 8-9 be withdrawn.

The Applicant submits that the application is now in form for issuance and respectfully requests reconsideration and an early allowance. If any issues remain, the Examiner is invited to telephone the Attorney at the number below.

Respectfully submitted,

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